1 INTRODUCTION

HEALTH CARE WORKERS TO USE PROTECTIVE BARRIERS[1]

The United States (U.S.) Centers for Disease Control (CDC) published a report on August 21, 1987, that emphasized the need for all health care workers to routinely use appropriate barrier precautions when contact with blood or other body fluids of any patient is anticipated.

On December 6, 1991, the U.S. Occupational Safety and Health Administration (OSHA) enacted regulations requiring the use of work practice controls and protective clothing, including gloves, to minimize worker exposure to blood-borne pathogens.

Subsequently, importation of medical gloves rose dramatically from 1986, when less than 1 billion gloves were imported, to 1997 when that number increased to about 23 billion. It is anticipated that gloves will be used increasingly to help prevent the transmission of Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other blood-borne pathogens.

The CDC report recommends that health care workers wear medical gloves when:

[1] Information on the regulatory requirements for patient examination gloves, surgeon's gloves, and some non-medical gloves is contained in this manual. To the extent this guidance discusses regulatory requirements, these are requirements established by the Federal Food, Drug, and Cosmetic Act or FDA's implementing regulations in Part 800 of Title 21 of the Code of Federal Regulations. Increased knowledge of regulatory obligations will result in increased compliance if manufacturers are willing to earnestly apply that knowledge. Although not specifically intended for other devices made of latex, such as dental dams, manufacturers should find that the general guidance in this manual is also helpful in meeting quality requirements for these devices.

- touching blood and other body fluids, mucous membranes, or non-intact skin of all patients;

- handling items or surfaces soiled with blood or other body fluids; and

- performing venipuncture and other vascular access procedures.

Because of the emphasis in the CDC recommendations upon gloves as a barrier to HIV, HBV and other blood-and-fluid borne infectious agents, and the need for greater assurance against transmission between patients and health care workers, the Food and Drug Administration (FDA) believes that gloves worn by health care workers must provide an effective barrier to the transmission of infectious agents. Obviously, this effective barrier can be provided by ensuring that medical gloves meet appropriate standards and prevailing guidelines.

REGULATORY AND QUALITY DEVELOPMENTS

FDA's regulations require that regulates medical gloves, requires that medical gloves be correctly labeled and cleared for marketing through a premarket notification submission [510(k)] prior to being distributed in the U.S. FDA's regulations at Title 21 Code of Federal Regulations Part 820 also require manufacturers to produce gloves according to the Quality System (QS) regulation (formerly Good Manufacturing Practices regulation) to assure that gloves are produced at an acceptable quality level, thus helping to assure their safety and effectiveness. The safety and effectiveness of medical gloves can be compromised by many kinds of defects. These defects can be controlled or eliminated through proper quality control procedures. The Agency has determined that glove defects, such as pinholes, which are not readily detectable by the users of gloves, can significantly compromise the effectiveness of the barrier and result in patients or health care workers being unnecessarily exposed to infectious agents. In order to increase the level of public health protection, FDA has taken several historical and recent actions as summarized below.

Historical Activities

From 1987 to the present, FDA has worked with manufacturers, standards groups, laboratories and the healthcare community to improve the safety and performance of gloves. The FDA:

- produced guidance, such as previous versions of this manual, to aid manufacturers in meeting FDA regulatory requirements and improving the quality of medical gloves;

- implemented (21 CFR 800.20) a more effective method for FDA to test for pinholes, and revised the FDA enforcement action levels to correspond with the new test method; and increased the sampling and testing of gloves;

- sent a letter to manufacturers in May 1991 advising them of allergenic problems with latex devices;

- conducted an International Latex Conference, Baltimore, Maryland, USA, Nov. 5-7, 1992 and conducted seminars on FDA requirements in most glove-producing countries;

- encouraged and supported the American Society for Testing and Materials (ASTM) in modifying existing standards and developing additional standards for medical gloves;

- encouraged manufacturers to develop gloves with low levels of chemical residues and water-soluble proteins; and

- encouraged manufacturers to test for "Quality at Delivery" and to provide verification data in their 510(k) submissions to show that their gloves will pass their acceptable quality level (AQL) for pinholes after real time testing or accelerated aging for 7 days at 70 degrees Centigrade or other appropriate protocol. "Quality at Delivery" does not involve a label claim. (This approach is expected to be replaced by the proposed expiration dating requirement.)

Recent Activities

A new regulation titled, "Natural Rubber-Containing Medical Devices; User Labeling" (http://www.fda.gov/cdrh/dsma/fr93097.html) became effective September 30, 1998 (see 21 CFR 801.437). The requirements of this regulation include the following two items:

Identity statement. The labeling of natural rubber latex devices must contain the statement, “Caution: This product contains natural rubber latex which may cause allergic reactions." This statement is also required by the proposed glove regulation.

Hypoallergenic claim. The labeling of natural rubber latex devices may no longer use the term "hypoallergenic."

Both of these requirements apply to all devices composed of or containing, or having packaging or components composed of or containing, natural rubber that contacts humans.

Chemical sensitivity. FDA has developed draft guidance for evaluating the chemical sensitization potential of medical devices containing latex and recommended labeling for products with reduced levels of chemical sensitizers. For guidance, please refer to the document titled, *"Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Latex Products,"* available on the Internet at: http://www.fda.gov/cdrh/ode/944.html.

Additionally, FDA has prepared a proposed rule regarding medical gloves that will be published in the *Federal Register*. The main features of this rule are summarized as follows:

Reclassification. FDA is proposing the reclassification of surgeon's and patient examination gloves to from Class I Class II because general controls are insufficient to assure their safety and effectiveness. The proposed Class II glove types are:

- powdered surgeon's gloves,
- power-free surgeon's gloves,
- powdered patient examination gloves, and
- powder-free examination gloves;

Protein levels. FDA, industry, and ASTM have developed a standard that uses the modified Lowry method for measuring water-soluble proteins on finished latex gloves. This standard, D-5712, was approved by ASTM in April of 1995. As of May 1, 1995, manufacturers started filing 510(k) submissions with FDA to reflect optional claims for protein levels on glove labeling based on measurements made according to D 5712. ASTM is working to improve this standard.

FDA is proposing in the noted regulation that all surgeon's gloves and patient examination gloves bear labeling that states the upper limit of water extractable protein per glove and the upper limit recommended by FDA which is no more than 1200 µg per glove.

Powder-free. ASTM, FDA, and industry have developed a standard method for measuring the residual or trace powder level on “powder-free” gloves. This ASTM standard D 6124 covers former-release powders, donning powders and manufacturing debris.

FDA guidance (this manual) recommends that powder-free surgeon's gloves and patient examination gloves contain no more than 2 mg trace powder per glove.

Powdered gloves. ASTM, FDA and industry are developing a standard for measuring the donning powder on a powdered glove.

FDA is proposing in the noted regulation that all surgeon's gloves and patient examination gloves bear labeling that states the powder per glove and state the upper limit recommended by FDA which is proposed to be no more than 120 mg per glove.

Expiration dating. FDA is proposing in the noted regulation that all surgeon's and patient examination gloves bear an expiration date that is supported by stability studies demonstrating acceptable physical and mechanical integrity during the shelf life.

QUALITY SYSTEM

FDA is emphasizing that to meet requirements in the QS regulation, manufacturers should implement controls to minimize:

- pinholes after accelerated or real time aging to help assure that gloves meet the manufacturers pinhole AQL when used by the customer;

- manufacturing chemical residues and water-soluble proteins;

- the amount of donning powder on powdered gloves to the lowest level needed for easy donning, thus reducing the amount of powder that could be released into the patient and the health care environment;

- the bioburden during the production of medical gloves; and

- the bioburden and moisture content of finished medical gloves.

VOLUNTARY STANDARDS

In addition to meeting regulatory requirements, medical gloves should conform to national voluntary consensus standards developed by industry, FDA and the:

American Society For Testing and Materials (ASTM)
100 Barr Harbor Drive
West Conshohocken, Pennsylvania 19428 USA
Phone: 610-832-9500
FAX: 610-832-9555

The ASTM standards for each type of glove is noted in appropriate sections of this manual. ASTM and other glove standards are listed in chapter 12.